UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,943	01/29/2004	Yasuyuki Numajiri	00862.023438.	1830

5514 7590 01/29/2009

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
01/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,943	NUMAJIRI, YASUYUKI	
	Examiner	Art Unit	
	AMANDA SHAW	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed November 13, 2008. This action is made FINAL.

Claims 28-33 are currently pending. Claims 28, 30, and 32-33 have been amended.

Withdrawn Rejections

2. The rejection made under 35 112 2nd in section 5 of the Office Action of August 13, 2008 is withdrawn in view of Applicants arguments.

The rejections made under 35 USC 102 in sections 7-9 of the Office Action of August 13, 2008 are withdrawn in view of amendments made to the claims.

The rejections made under 35 USC 103 in sections 11-12 of the Office Action of August 13, 2008 are withdrawn in view of amendments made to the claims.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejected claims are drawn to a testing method using a DNA microarray. The rejected claims are drawn to methods which comprise steps of reading hybridization patterns, analyzing hybridization patterns, comparing information and outputting information to a storage medium.

In re Bilski No. 2007-1130 (Fed Cir. October 30, 2008) characterizes its machine-transformation test as "the governing test for determining patent eligibility of a process under section 101 ." Under this test, a process claim is patent-eligible if (and, as applied in Bilski, only if): "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."

In the instant case the claims are not tied to a particular machine because all of the steps can be performed mentally. For example reading a hybridization pattern, analyzing a hybridization pattern, and comparing a hybridization pattern can all be performed by just looking at the array. Further the step of "outputting the test information to a storage medium" can be performed by storing the information by memory (i.e. in ones brain which is technically a "storage medium"). As such the methods as claimed are not tied to a particular machine. Additionally the claims do not transform a particular article. Therefore the claims are not directed to patent eligible subject matter since they are not tied to any particular machine and they do not require any particular article to be transformed into another state or thing.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a new rejection necessitated by amendment:

5. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Hogan teaches a method wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated by hybridizing a genomic DNA sample to a DNA microarray and detecting hybridization (Para 0167-0176 and Para 210). Genomic DNA samples are expected to include genes suitable for personal identification and disease related genes. Thus Hogan teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to

identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject (Para 0167-0176). Hogan teaches that after the sequence information has been generated the information can be stored (e.g., as digital information on a portable chip) (para 0186). Thus Hogan teaches a method further comprising storing test information into storing means.

Hogan does not teach a method wherein the microarray has two separated areas, wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject.

Therefore, modifying the method of Hogan by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hogan does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card and only generating test information if the identification information on the medical card and microarray match.

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as

suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information.

The following is a new rejection necessitated by amendment:

6. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (US 2005/0064436 Filed 3/2005) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid sample, where the determined SNP profiled is then employed to identify the source of the sample, e.g., the subject or patient from which the sample was obtained. Barrett further teaches that the sample can also screen for a condition, e.g., a disease. In some embodiments the sample is screened for a SNP profile and a disease simultaneously using an array of probes wherein the array includes both SNP probe features and disease probe features (para 0063). Barrett teaches that the sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes. Thus Barrett teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of

the subject and obtain health related test information for the subject. Barrett further teaches that after the sequence information has been generated the information can be stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett teaches a method further comprising storing test information into storing means.

Barrett does not teach a method wherein the microarray has two separated areas, wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Barrett by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Barrett does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card and only generating test information if the identification information on the medical card and microarray match.

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information.

The following is a new rejection necessitated by amendment:

7. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi (US 2004/0048259 Filed 9/2002) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

Hashmi teaches a method for genetic testing of an organism and for correlating the results of the genetic testing with a unique marker (i.e. SNP profile) that unambiguously identifies the organism (Abstract). Hashmi teaches that patients sample is contacted with a first set of probes that is used in an assay designed for genetic testing and the second set of probes is used in the determination of a molecular fingerprint (para 0089). Hashmi further teaches that the patients sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes (para 0061). Thus Hashmi teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hashmi further teaches that after the sequence information has been generated the information can be stored in a database (para 0131). Thus Hashmi teaches a method further comprising storing test information into storing means.

Hashmi also teaches that if subsequent testing is performed the results of the second test may be verified unambiguously by comparing the genetic fingerprints associated with the first and second tests. Thus Hashmi teaches comparing first and second identification information.

Hashmi does not teach a method wherein the microarray has two separated areas, wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hashmi because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Hashmi by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hashmi does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card and only generating test information if the identification information on the medical card and microarray match.

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information.

Response To Arguments

8. In the response filed November 13, 2008, the Applicants stated that claims 32 and 33 have been amended to clarify that test information is generated and outputted to a storage medium. Based on this amendment they Applicants submit that claims 32 and 33 satisfy the requirements of 35 USC 101 as recently articulated in the In re Bilski case.

This argument has been fully considered but is not persuasive. According to the In re Bilski decision a patentable process must either (1) be tied to a particular machine or (2) transform a particular article. In the instant case the claims are not tied to a particular machine because all of the steps can be performed mentally. For example reading a hybridization pattern, analyzing a hybridization pattern, and comparing a hybridization pattern can all be performed by just looking at the array. Further the step of "outputting the test information to a storage medium" can be performed by storing the information by memory (i.e. in ones brain which is technically a "storage medium"). As such the methods as claimed are not tied to a particular machine. Additionally the claims do not transform a particular article. Therefore claims 32 and 33 remain rejected under 35 USC 101.

Regarding the art rejections the Applicants amended the claims to overcome the prior art of Hogan, Barrett, and Hashmi. Specifically the claims now require a DNA

microarray with two separate areas, wherein the first region has probes for personal identification and the second region has probes for checking on a health condition. The Applicants argue that the previously applied references fail to disclose or suggest using a DNA microarray that has two separate areas. This argument has been fully considered and was found persuasive however the Examiner has provided new art rejections based on the claims as amended.

Further the Applicants argue that claims 32 and 33 as amended require comparing identification information from the microarray with identification information stored in a storage device and analyzing the hybridization state of the second DNA probe group only if the comparison indicates that both sets of identification information match. This argument has been fully considered but is not persuasive Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match.

Further the Applicants argue that claims 32 and 33 clearly indicate that the hybridization state of the second DNA probe group is analyzed only when the

information is determined to match. This argument has been fully considered but is not persuasive. In view of the "comprising" language of the claims, the claims are not actually limited to a method wherein the hybridization state of the second DNA probe group is analyzed only when the information is determined to match because the claims can accomplish additional steps. Even if the claims were limited to this Beecham states that when the biometric data does not match the stored biometric data, no test information is released (Col 18, lines 14-19).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Carla Myers/
Primary Examiner, Art Unit 1634